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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,010	09/19/2000	Daniel R. Ansley		5081

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
666,010	ANSLEY
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 2/19/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-27 is/are pending in the application.

Of the above claim(s) 1-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 21-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☑ The drawing(s) filed on 9/19/00 is/are ~~objected to by the Examiner.~~ APPROVED BY THE DRAFTSMAN.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Claims 1-27 are pending.

Applicant's election without traverse of Group III (claims 21-27) in Paper No. 3 (filed on 2/19/02) is acknowledged.

It is noted that the response of 2/19/02 traversed the requirement of an election of species, and elected as species components of 60,000 dalton or less, from a goat source, to treat a canine species for a parvovirus challenge. A notice of a non-responsive amendment was mailed on 3/11/02 (Paper 4).

Upon reconsideration, the examiner has withdrawn the election of species requirement. It is noted that applicant's own patent 5,219,578 contains claims to the treatment of a variety of mammalian species for a variety of named disease states.

The specification is objected to under 37 CFR 1.52. Specifically, pages 17-18 have tables that extend beyond the limits required for margins. This has resulted in punch hole obliteration of the right edge of Table 2.

Rewritten specification pages are required for pages 17-18. See 37 CFR 1.125 and MPEP 608.01(q).

Claims 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 must be amended to include the limitations of non-elected base claim 1.

Claims 22-27 are each unclear in line 1 by reciting "the mammal". Is this the mammal from which the blood components are obtained or the mammal being treated?

Claims 21-27 provide for the use of a composition of blood components , but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 22-27 are each unclear by reciting "canine species", "bovine species" etc. Each of the recited members is a --Family--, not a "species", according to the classification system of Linnaeus.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thorbecke et al. (4,702,808), as evidenced by Maione et al. (5,086,164) and in view of Nagai et al. (5,464,816).

Thorbecke et al. teach the use of whole human serum containing the immunostimulating polypeptide platelet factor 4 (PF4) to treat immunosuppressed mice. See col. 3, lines 53-57 and col. 4, lines 11-12. See also Examples 2-4 and 6, for example. It is to be noted that PF4 is a polypeptide inherently having molecular weight of about 7,800 daltons, as evidenced by Maione et al. at col. 2, lines 19-26. This polypeptide would thus fall within applicant's claimed limit of 60,000 daltons and within applicant's further disclosed limit of 8,000 daltons.

Nagai et al. teach that mammalian sera contain a non apeptide (ca. 1000 daltons) designated as serum thymic factor (FTS) which has immunostimulating activity and which can be used to treat immunodeficiencies. See col. 2, lines 10-30 and col. 3, lines 2-17, for example.

Given that low molecular weight immunostimulating polypeptides such as the PF4 of Thorbecke et al. and the FTS of Nagai et al. were known to exist in mammalian serum, it would have been obvious to obtain a low molecular weight fraction (e.g. with a cut-off M.W. of 8000 daltons), in lieu of whole serum, for the therapeutic administration of these polypeptides. Motivation to use such a low molecular weight fraction comes from the fact that it is known that whole serum contains numerous high molecular weight proteins, which would induce undesired immune responses in the treated mammal. See, for example, Nagai et al. at col. 4, lines 41-45.

One would have been motivated to do so in the case where one is administering the peptide components across species (to prevent xenogeneic responses) or within species (to prevent allogeneic responses).

Also, by administering a fraction of serum containing low molecular weight polypeptides, one would have expected that one would gain the advantage of administering more than one immunostimulating polypeptide --e.g. one would thus administer both the PF4 of Thorbecke et al. and the FTS of Nagai et al. and thereby achieve at least two immunoenhancing effects.

Claims 22-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorbecke et al. in view of Nagai et al. as applied to claim 21 above, and further in view of Ansley 5,219,578.

Thorbecke et al. and Nagia et al. have been cited for the obviousness of administering a fraction of serum containing low molecular weight polypeptides in order to provide an immunostimulating treatment. One would have reasonably expected that such treatment would enable a mammal to show enhanced immunonesponsiveness to numerous known infectious agents to which it is commonly exposed. Ansley shows that it is of interest to immunostimulate canines again parvovirus (Example 7) as in instant claims 22-23, bovines against shipping fever (Example 5) as in instant claim 24, and equines against lower respiratory disease, as in instant claim 27. Note that "respiratory infection" encompasses what Ansley teaches and that "lower airway disease" is understood to be the same as "lower respiratory disease" of Ansley. The limitations of dependent claims 22-24 and 27 thus would have been obvious.

Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorbecke et al. in view of Nagai et al. as applied to claim 21 above, and further in view of Fraser et al. (Merck Veterinary Manual).

Thorbecke et al. and Nagai et al. have been cited for the obviousness of administering a fraction of serum containing low molecular weight polypeptides in order to provide an immunostimulating treatment. One would have reasonably expected that such treatment would enable a mammal to show enhanced immunoresponsiveness to known infectious agents to which it is commonly exposed.

Regarding claims 22-23, Fraser et al. teach (pages 249-250) that parvoviral infections are a known disease of canines. A further basis for obviousness of the claimed treatment is that any low molecular weight fraction of serum would contain balanced salts as well as low molecular weight peptides. Administration of such a salt balanced fluid would provide the fluid therapy taught by Fraser et al. (para. spanning pages 249-250). Further, since Thorbecke et al. teach use of PF4 as an adjuvant (col. 5, lines 11-19), one would have been motivated to use such as an adjuvant in the immunization treatments taught by Fraser et al. (Page 250).

Regarding claim 24, Fraser et al. teach shipping fever as a known disease affecting bovines (pages 723-724). They teach immunizations (page 724, third para.); and, as argued above regarding claims 22-23, provision of serum PF4 as an adjuvant would have been obvious for immunizations.

With respect to claim 25, Fraser et al. teach enteritis as a type of disease known in porcines (pages 195-197). They teach maintaining hydration and immunization (page 197, third para.). As noted supra for claims 22-23, administration low molecular weight serum would provide for hydration and it would provide an adjuvant for immunization.

Regarding claim 26, Fraser et al. teach (page 39) that Feline leukemia virus causes immunosuppression. Thus it would have been obvious to employ an immunostimulating serum composition containing PF4 of Thorbecke et al. and FTS of Nagai et al. to treat this condition in felines.

With respect to claim 27 Fraser et al. teach (pages 854-855) that equines can develope warts (papillomas) and that vaccination can be used to control the disease in herds. Since Thorbecke et al. teach use of serum PF4 as an adjuvant in vaccinations/immunizations, it would have been obvious to employ such an adjuvant in the immunizations taught by Fraser et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

November 7, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644